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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,814	10/30/2003	David Goldberg	D/A3535	1311

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MICHAEL R. MCCARTHY
PARSONS BEHLE & LATIMER
201 S. MAIN ST.
SUITE 1800
SALT LAKE CITY, UT 84111-2218

EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/696,814

Applicant(s)

GOLDBERG, DAVID

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/30/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on 08/06/07 is acknowledged. Claims 1-11 and 21-28 are pending in the application.

Response to Amendment

2. Objection to the drawings and the specification remains and expanded and rejection of the pending claims is changed in light of the Applicant's amendment.

New Matter

3. The amendment filed on 08/06/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: "developing a rule set generated from an initial set of archetypes entered into an associated directory of the cartoons" (claims 3).

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

4. Schematic algorithm of the method steps depicted on Figures 3-6 cannot be considered an illustration to the claimed invention, since it is not quite apparent, as to what the "monosaccharide set table" is, how peak identification is performed, and what is the results summary (Figure 3). It is further unclear, as to what are "monosaccharide combination ranges", what type of "rule set" should be developed, etc. The examiner considers the method steps depicted on Figures 3-6 more appropriate for description in the text with full explanation of the steps. The examiner also believes that illustrative examples for performing method, such as representing monosaccharide set table and assigning cartoons to the peaks in an exemplary mass spectrum, are necessary for better understanding of the invention.

Thus, the Applicants are required to furnish additional drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

The required drawings must illustrate at least one row of the monosaccharide set table comprising 5 HexNAc and 4 Hexoses with a particular mass (page 6, subparagraph [0025] of the specification); the drawings must illustrate assigning glycan cartoons to mass spectral signals.

Specification

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as not containing “a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains” to make or use the invention in its best mode. First, it is not apparent, as to how the references fully incorporated into the instant application are related to the instant invention, since they refer to totally different chemical entities, i.e. peptides and proteins, which are analyzed by different algorithms. Further, it is not apparent from the specification, which mass spectra of glycans are analyzed - mass spectra of unfragmented ions or mass spectra of glycan fragments, which would require different algorithms, since calculating masses of all possible fragments of a particular glycan is different from calculating a mass of the unfragmented glycan. Also, “cartoons” would be different for fragmented and unfragmented glycans. The description provided for the term “cartoon” as “a symbolic representation of a particular row from an associated monosaccharide table” is still not satisfactory regarding the clarity of the term, since it is not apparent, as to how one symbol can represent the whole row from the table presumably representing different monosaccharides.

It is not apparent, as to what the expression “each glycan spectrum including peaks having a measured mass” (page 2, [0004]) might be. All peaks have their masses assigned to them. Which types of special peaks “having a measured mass” are meant in this expression?

In paragraph [0005] it is not apparent as to what is “a maketable module”, which constructs a monosaccharide set table.

Paragraph [0025] is not clear in its fundamental description of the invention. It appears from the paragraph that in order to construct a monosaccharide set table the experimenter should propose all potential glycans, which can be present in the sample. Such assumption is not clear in light of the major purpose set by the Applicant in the Background of the Invention, in which he specifically indicates that “a key problem in proteomics is the identification of these glycans” (page 1, [0003]). It is not apparent, as to how it would be possible to assume, which potential

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glycans are present in the sample, if the glycans are unknown? If there is a reasonable assumption that the specific glycans are present in the sample, then it is not apparent, as to why any table should be constructed at all, if the theoretical masses of the assumed glycans can be directly compared with the experimental masses?

Specifically, paragraph [0025] discloses a program component 110, the maketable program, which constructs a monosaccharide set table, "composed of potential glycans generated by using all possible sets of monosaccharides within a range set by the experimenter". Does it mean that the experimenter should input all possible monosaccharides existing in nature (all of which can be a part of glycoproteins with unknown glycans to be identified)? The expression "each row of the table contains a set of potential glycan isomers, its theoretical mass, and the probability of each isotopes" is totally unclear. What is meant by the terms "potential glycan isomers", "its" theoretical mass (which "its"?) and "the probability of each isotopes" [how can it be, "each isotopes"?]? Which "isotopes" the paragraph refers to? Which "potential glycan isomers"? Does the Applicant call different glycans with coinciding molecular masses the "glycan isomers"? The term "glycan isomer" is not defined in this way. What does it mean, "the identification component 120 reads monosaccharide set table 150" - the whole table? Each row? Does the table contain all possible combinations of all possible monosaccharides?

Paragraph [0026] provides a part of the mass spectrum for what? Is this an experimental data? What is it supposed to show? Is this a molecular ion of a particular glycan in a digital representation? The examiner does not quite understand, what this table should represent.

Paragraphs [0027] and [0028] are not clear. It is not apparent, as to how "summary component 130" utilizes "cartoon dictionary", and who or what creates such cartoon dictionary? What is "the isomer with 5 HexNAcs and 4 Hexoses" - it is an isomer of which another glycan? The abbreviation "5HexNAcs" should be explained. The term "isomer" has a very specific meaning in carbohydrate chemistry, and conventionally stands for "chiral" or "optical" isomer. It seems that the Applicant uses this term in an unconventional meaning. The examiner would like to remind the Applicant that "where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

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Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999)". The examiner does not find any specific and clear definition of the term "isomer" as the Applicant uses it. Especially it is not clear in view of the representation of different isomers of the same glycane in Table on page 8 (paragraph [0033]. Why the glycan will be the same, if it contains 3 and 4 hexoses? The examiner is quite confused, as to what is depicted in the table and respectfully requests the Applicant's clarification of this matter. In the same paragraph the term the "frequency of isotopes" is mentioned. Which "isotope frequency" the specification refers to? What are isotopes "+0", "+1", "+2", "+3"? The examiner respectfully requests the Applicant's clarification as to what these isotopes are.

It appears that in order to understand the proposed method the Applicant needs to provide a specific example as to how all steps of the inventive method are performed, starting from the very beginning. The examiner does not consider the disclosure in its present format is understandable by a routineer in the art, and therefore it does not appear to be enabling for a routineer in the art.

The examiner further would like to indicate that a full and clear description of the inventive method is provided in the article of Goldberg et al. "Automatic annotation of matrix-assisted laser desorption/ionization N-glycan spectra" published in Proteomics in 2005. Without reading this article the instant disclosure cannot be understood. The specification lacks enabling disclosures provided in the paper.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-11 and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As shown above, the specification does not adequately describe "assigning

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glycan identifications to said peaks by comparing and measuring mass to known masses of a customized set of possible glycans in a monosaccharide table”, since the specification does not provide any guidance as to how to build the monosaccharide set table and provide a customized set of possible glycans for a sample comprising unknown glycans. Because the specification does not enable the step of assigning, it does not enable any further steps of the method recited in claim 1.

The specification does not adequately define such essential terms for the instant application, as “glycan isomers” and “isotope frequencies”. In both cases the terms are conventional for the fields of carbohydrate chemistry and mass spectrometry, respectively, and apparently have different meanings from those used in the instant application. This not only renders the claims unclear and indefinite (see the next paragraph), but also makes the disclosure unenabled for performing the steps referring to these terms.

Claim 3 recites the expression “generated from an initial set of archetypes entered into an associated directory of the cartoons”, which is unsupported by the specification.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-11 and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 recites “includes peaks having a measured mass” (why a plurality of peaks have only one measured mass?). This expression is not apparent, as it is not clear, which else peaks can be obtained in a mass spectrum.

The step of “combining said peak assignments with cartoons” is not apparent. It is not clear, as to what such symbolic representation provides for assigning the peak of glycans in mass spectra?

As it was indicated above, the claims recite such terms as “isomers of glycans” and “glycan isotope frequencies”, which are not defined in the specification and which render the claims unclear and indefinite, since the meaning of these terms do not appear to be a conventional meaning in the art.

Claim 3 recites a new matter, as it was indicated above.

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In general, the language of the claims follows that of the specification (except for the new matter of claim 3); as it was demonstrated above, the language of the specification cannot be considered clear and definite, which renders the claims unclear and indefinite.

Response to Arguments

10. Applicant's arguments with respect to claims 1-11 and 21 have been considered but are moot in view of the new ground(s) of rejection.

The examiner would like to note, however, that incorporating by reference two patent application publications, which while related to computerized assigning signals in mass spectrometry, are not directly related to assigning the signals of glycans based on cartoon representation. This makes it unclear, as to what specifically is incorporated by reference in the present application, since computer-assistant assignment of the signals in mass spectra of various biomolecules is well known in the art and is published in hundreds of papers.

The examiner considers the instant specification, which is related to a non-trivial assignment of glycan signals in mass spectra using a new algorithm based on cartoon representation, insufficient for enabling the claimed invention. By comparison to fourteen pages of a broadly and fragmentary written specification, with at least several of the pages representing tables without specific description of their content (e.g. Table on page 6), the full article devoted to exactly the same method occupies ten pages of a print format, is accompanied with a full and detailed description of the method and illustrated with examples and spectra. The examiner believes that a person of an ordinary skill in the art cannot understand the instant disclosure without first reading the paper by Goldberg et al.

The examiner invites the Applicant and his representative for an interview if they believe that this may assist the prosecution of the case. However, the examiner believes that the disclosure in its present format is not enabling and not patentable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yelena G. Gakh, Primary Examiner
/Yelena G. Gakh/

09/17/07